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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,791	08/05/2002	Piet Herdewijn	0702-020249	9473

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,791	HERDEWIJN ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/26/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39,41,43 and 44* is/are pending in the application.

4a) Of the above claim(s) *8,9,11,13 and 24-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10,12,14-23,35-39,41,43 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/8/2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/2006 has been entered.

Election/Restrictions

The petition decision of 6/2/2005 is noted; the petition was denied. Hence, claims 1-7, 12, 14-23, 35-39, 41 and 43-45 continue to be objected to as having non-elected subject matter present. This material must be removed. Limitation to the adenines, which is what has been examined, will resolve the matter.

The remarks on page 19-20 are noted, but as indicated above, this is matter has already been ruled upon in the petition. As for "reasonable number of additional species" situation, this case has had a requirement for restriction, not election of species. Applicants have elected the class of adenines.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejections over Maurinsh, et al. and Konkel, et al. were previously overcome by removal of X = H subject matter. The rejections over Gannett et al, and Hiramoto were previously overcome by the limitation to a single double bond in the carbocyclic ring.

Claims 1-7, 10, 12, 14-23, 35-39, 41, 43-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Wang (2000) or Wang (1999).

The references were published before the filing of the PCT application, and inventorship is different from authorship, but the same subject matter is disclosed. The rejected claims are not entitled to benefit of any of the US provisional applications. None of these applications have the scope of genus as seen in the rejected claims. A great deal of material was added to the PCT application which was not in any given US provisional application.

The previous traverse was unpersuasive. Applicants conceded that the rejected claims are broader than the provisional applications, but say instead that the references are "nearly identical" to these provisional applications. This argument has no legal merit. It would not matter if the prior art reference were all within the scope of the priority applications. The priority date for claims is determined without reference to the contents of the prior art reference. Once the claims have been determined to lack benefit, they are properly rejected, even though the reference contains no more than the priority application.

Attention is drawn to *In re Schreiber*, 199 USPQ 782, which had this exact situation. Note also *In re Albrecht*, 168 USPQ 293.

The new traverse is unpersuasive. It appears that an impasse has been reached. Applicants are again urged to review *In re Schreiber*, 199 USPQ 782, which has the current fact situation. Applicants give an "analogous example". The examiner agrees that this example is analogous, but in that example, the anticipation rejection would indeed be sound. The remarks conclude "The publication disclosing copper cannot be considered anticipatory *because the subject matter of copper* in the application, which falls within the scope of claim 1, *is entitled to claim priority* to the provisional application." Emphasis added; it is this material which is legally in error. Priority is determined at the level of the claim itself, not the "subject matter" of the claim. In other words, if any aspect of the claim is not entitled to priority, then the claim as a whole is not entitled to benefit, even if that aspect is wholly absent from the reference. Applicants can gain benefit only by removing all material lacking benefit from the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-23, 35, 41, 43-44 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 15 "providing" is unclear. Does this mean manufacturing the XII, and if so, how? Of does it just mean something like "reacting with".
2. What does "related viruses" in claims 41 and 43 refer to? Which families are considered related? Does this term include Iridoviridae? Polydnaviridae? Polyomaviridae? Papillomaviridae? Adenoviridae? Ascoviridae? Baculoviridae? Nimaviridae? Asfarviridae? It is noted that Herpes and Pox viruses are both DNA viruses families. Does "related viruses" perhaps mean all DNA viruses? The traverse is unpersuasive. All viruses are to some degree related in that all viruses are noncellular biological entities which consist of nucleic acids covered by protein and can reproduce only within a host cell. Applicants state, "the term "related viruses" includes all viruses that are related to the identified virus", but that is simply a tautology. Applicants have not answered a single question posed, and if applicants cannot answer such straightforward questions, then the term is unclear on its face. Simply pointing to a book does not answer the question.
3. What would an "analogue" cover in claim 19. The earlier traverse was unpersuasive. Applicants stated that it "may be dialkyl analogues, such as benzaldehyde dialkyl acetal." How is that an analogue? It's a protected version. Now, applicants argue that "one of ordinary skill in the art would know which benzaldehyde analogue can be used for this purpose", but that in no way answers the question. Knowing which analogues

will work and which will not work doesn't answer the question of which compounds are analogs in the first place.

Claim 20 is rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

This reaction is impossible. Thus, it is either written wrongly (paragraph 2) or if written correctly, is not enabled (paragraph 1). A reductive process will not remove the alkyl or alkenyl from the alkoxy or alkenyloxy of XVB. In fact, cleavage of such a group requires a reagent such as concentrated HBr, which will add to the ring double bond and hence would be unsuitable.

Second, the examiner cannot locate this reaction in the specification, and hence is lacks description in the specification ((paragraph 1)).

The traverse is unpersuasive. Applicants again point to the page 32 reaction. The examiner against states that this, does not show the cleavage of an alkyl or alkenyl from the alkoxy or alkenyloxy (cleavage of ether), but rather shows the cleavage of a an acetyl group from an acetoxy (cleavage of ester). Such a ester cleavage is quite conventional and can even be done by hydrolytic agents. Cleavage of an ether to an OH requires, as stated above, a reagents such as HBr.

Second, page 32 does not constitute a description of this reaction. Page 32 is just $LiAlH_4$; it does not say reduction in general. Second, it does not teach that XVB will undergo such a reaction.

The current remarks have not addressed either of these points.

Claims 1-5, 15-17, 20-23, 36-39, 41, 43-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The provision wherein R1 and R2 are combined to form a protecting group lacks description in the specification. XIII in claim 18 is an example of such a combined protecting group, but the specification does not teach the generic concept of any such protecting group which protects two oxygens simultaneously.

Applicants point to the species on page 34 (same is XIII). Applicants conceded that this is just one species, but say that one could "extrapolate this teaching...." However, such reasoning is not legally valid. Even if all combined groups would be obvious, that is not he legal standard. Description must be provided for exactly what is claimed, "Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed." *Lockwood v. American Airlines*, 41 USPQ 2d 1961, 1966.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for herpes viruses, does not reasonably provide enablement for pox viruses generally or "related viruses". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Poxviruses are very large viruses about the size of small bacteria. They have a complex internal structure - a large double-stranded DNA genome (about 200 kbp in size) is enclosed within a "core" that is flanked by 2 "lateral bodies". The scope of pox viruses is quite extensive, in part because there are so many genera, many of which have numerous species present. The Orthopoxvirus genus includes Camelpox, Cowpox, Ectromelia virus, Mousepox, Taterapox, Vaccinia virus, Buffalopox, Rabbitpox, Variola virus (smallpox), Volepox, Skunkpox, and the Uasin Gishu disease virus. The Parapoxvirus genus includes Bovine papular stomatitis virus, Orf virus, Parapoxvirus of red deer in New Zealand (PVNZ), Pseudocowpox virus (PCPV), Squirrel parapoxvirus. Auzduk disease virus, Camel contagious ecthyma virus, Chamois contagious ecthyma virus and Sealpox virus. The Avipoxvirus genus includes Canarypox, Fowlpox, Juncopox, Mynahpox, Pigeonpox, Psittacinepox, Quailpox, Sparrowpox, Starlingpox, Turkeypox, Crowpox, Peacockpox, and Penguinpox. The Capripoxvirus genus has Goatpox, Lumpy skin disease virus (LSDV) and Sheeppox. The Leporipoxvirus genus has Hare fibroma virus, Myxoma virus, Rabbit fibroma virus, Shope fibroma virus, and Squirrel fibroma virus. The Suipoxvirus genus has just Swinepox, and the Molluscipoxvirus genus has just Molluscum contagiosum virus (MOCV). The Yatapoxvirus genus has Tanapox virus and Yaba monkey tumor virus. The Entomopoxvirinae genus has Anomala cuprea entomopoxvirus, Aphodius tasmaniae entomopoxvirus, Demodema boranensis entomopoxvirus, Dermolepida albohirtum entomopoxvirus, Figulus subleavis entomopoxvirus, Geotrupes sylvaticus entomopoxvirus, Melolontha melolontha entomopoxvirus, Othnonius batesi entomopoxvirus, Phyllopertha horticola entomopoxvirus and Ips typographus entomopoxvirus. The Betaentomopoxvirus genus includes, Acrobasis zelleri entomopoxvirus 'L', Amsacta moorei entomopoxvirus 'L',

Amsacta moorei entomopoxvirus 'L', Arphia conspersa entomopoxvirus 'O', Choristoneura biennis entomopoxvirus 'L', Choristoneura biennis entomopoxvirus 'L', Choristoneura conflicta entomopoxvirus 'L', Choristoneura diversuma entomopoxvirus 'L', Choristoneura fumiferana entomopoxvirus 'L', Choristoneura fumiferana entomopoxvirus 'L', Chorizagrotis auxiliars entomopoxvirus 'L', Heliothis armigera entomopoxvirus 'L', Heliothis armigera entomopoxvirus 'L', Locusta migratoria entomopoxvirus 'O', Oedaleus senigalensis entomopoxvirus 'O', Operophtera brumata entomopoxvirus 'L', Schistocera gregaria entomopoxvirus 'O'and Pseudaletia separata entomopoxvirus 'L'. The Gammaentomopoxvirus genus includes Aedes aegypti entomopoxvirus, Camptochironomus tentans entomopoxvirus, Chironomus attenuatus entomopoxvirus, Chironomus luridus entomopoxvirus, Chironomus plumosus entomopoxvirusand Goeldichironomus haloprasimus entomopoxvirus. In addition there are numerous pox viruses which have not even been assigned to a genus, including Diachasmimorpha entomopoxvirus, Melanoplus sanguinipes entomopoxvirus 'O', California harbor seal poxvirus, Cotia virus, Dolphin poxvirus, Embu virus, Grey kangaroo poxvirus, Marmoset poxvirus, Molluscum-like poxvirus, Mule deer poxvirus (which it has been recently asserted belongs in its own genus), Nile crocodile poxvirus, Quokka poxvirus, Red kangaroo poxvirus, Salanga poxvirus, Spectacled caiman poxvirus, Vole poxvirus and the Yoka poxvirus.

Because of the great diversity of these viruses, which arises in part due to the wide range of mammals and birds that these infect, for a compound to work generally against these is contrary to present medical knowledge. Indeed, there is presently no agent which is effective against even a small range of pox viruses. Currently, the only marketed antiviral that has inhibitory effects on any poxvirus is cidofovir, which, however, as of yet has not

been established as effective for the treatment of any pox disease, despite research on the matter which has gone back to 1998.

As noted above in point 2, there is no way of knowing what the scope of "related viruses" is.

Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006. When operativeness has been properly challenged, it is incumbent on applicant to limit the claims accordingly, cf. *In re Harwood*, 156 USPQ 673, *In re Cook*, 169 USPQ 298, I*n re Langer*, 183 USPQ 288, *In re Corkill*, 226 USPQ 1005, 1009, and *In re Rainier*, 153 USPQ 802.

The traverse is unpersuasive. Applicants have not come to terms with the extreme diversity of pox viruses, and the fact that no human disease arising from pox viruses have been successfully treated with antivirals.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Berch
Primary Examiner
Art Unit 1624

12/5/06